大阪市立大学看護学雑誌　第3巻（2007. 3）

The Nurse's Role in Informed Consent, Problems and Perspectives

インフォームドコンセント(IC)における看護者の役割—問題および展望

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キーワード：インフォームド・コンセント、看護者の役割、問題
Key words : Informed consent (IC), Nurse's Role, Problem

Abstract

The purpose of this paper is to discuss the role of nurses in informed consent. Two cases illustrate some problems surrounding informed consent which nurses may experience in their nursing practice. The criteria for informed consent provides the essential elements necessary for informed consent.

It is generally agreed that nurses do not have the primary responsibility for getting informed consent. The nurse's primary responsibility in informed consent is to explain the nursing care.

Introduction

Informed consent means consent in which a person has received sufficient information concerning the health care proposed, its incumbent risks, potential benefits of care, and acceptable alternatives. The common rule requires that all patients or their legal guardians, through a free and rational act that presupposes knowledge of the thing to which consent is given by a person who is legally capable of consent, sign a consent form detailing what care he or she desires. The informed consent given prior to any medical and surgical intervention is an absolute requirement in non-emergency situations and requires a signed consent form. (Kass, 2003).

However, for years, when patients were admitted to a hospital they signed a frequently unread universal consent form that almost literally gave the physician, his or her associate, and the hospital a free hand in the patient's care. Those patients undergoing surgery or a complex invasive procedure were asked to sign another form, usually stating that they would permit physician and/or his or her colleagues to perform the operation or treatment. Just how much the patient knew about the surgery or procedure, the risks, and the alternatives, depended on the patient's or his legal guardian's assertiveness in asking questions and demanding answers, as well as the physician's willingness to provide information. In Japan, nurses were taught not to answer these questions but to suggest the patient that they should "ask your doctor." Health professionals, especially physicians, took the attitude that they know best and that will decide the patients. Many patients probably still enter treatment and procedures without a clear understanding of the nature of their condition and what can be done about it. (Morioka. 1996, Sugita. 1994)

Although they may be receiving care that is medically acceptable, they have no real part in deciding what that care should be.

Most physicians believe that anything more than a superficial explanation is unnecessary since patients should trust the doctor. Yet, patients have always had the right to make decisions and to choose whether they desire medical care or not. (Jogahana, 1990)

In hospitals, nurses are frequently asked to witness

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a patient's signature for informed consent. To do so, the nurse must be certain what is being witnessed, i.e., signature only, or signature for informed consent. The purpose of this paper is to discuss the criteria for informed consent and the nurse's role in informed consent. Descriptions of two actual cases will illustrate the problems which nurses may experience in their nursing practice.

Case A

Mrs. A, 40 years old, held a managerial position in a life insurance company. Her family consisted of a husband, 45 years old who was a government employee, a 17-year old son, daughters, 14 and 8 years old, and a 68-year old mother-in-law.

Mrs. A had begun to have irregular vaginal bleeding three years earlier. She saw a local physician, Dr. X, for her vaginal bleeding and was diagnosed as myoma uteri.

She had been receiving care from Dr. X regularly for the past three years. Medication had been prescribed for Mrs. A's vaginal bleeding, but Dr. X provided vague information concerning the medication and prognosis of her condition. Mrs. A's irregular vaginal bleeding continued without improvement despite treatment. Often her vaginal bleeding incapacitated her from work. Furthermore, Mrs. A's lumbago became worse.

At this point, Mrs. A decided to seek another physician's care at the Medical University Hospital. After many examinations and tests, she was diagnosed with uterine cancer and was advised by a doctor to go for surgery as soon as possible.

This unexpected uterine cancer diagnosis brought the whole family an emotional turmoil. For the past three years, under the care of Dr. X, she was led to believe that she had a myoma uteri and not cancer. Both she and her husband were the financial supporters of the family. This cancer diagnosis left them with an extreme state of stress and grief. To complicate the situation further, to be admitted to the Medical University Hospital was thought to be "doomed for hopeless future." It was believed by the people in Mrs. A's community that those admitted to the Medical University Hospital were those with serious illnesses without the prospect of recovery, or those on the verge of death.

After Mrs. A's admission to the hospital, the nurses who provided care for her listened to her frustration and grief. The nurses communicated the patient's feeling and concerns to the physician and also recorded this information in her chart. The physician, accompanied by nurses, visited Mrs. A before surgery and, in lay term language, explained the purpose of the surgery, procedures of the operation, possible benefits and risks, post-operative treatment, and alternatives. The patient and her husband were asked to discuss and decide whether to accept or decline the pending surgery and cancer therapy. After discussion, Mrs. A decided to accept the surgery and cancer therapy. The nurse was called in to witness Mrs. A's informed consent signature. The surgery was successfully performed.

Case B (An example of a controversial case: the patient was told he had liver disease while his family was told the patient had liver cancer.)

Mr. B, 72 years old, unemployed, had been diagnosed liver cancer with metastasis to the large intestine. His family consisted of his wife, 68 years old, a son, 45 years old, the son's wife, 43 years old, and two grandchildren, an 18-year old college student, and a 16-year old high school student.

Mr. B had complained of constant general malaise and loss of appetite over the previous six months. After various tests at the hospital, he was diagnosed with liver cancer with metastasis to the large intestine. However, it was explained to the patient by his doctor that he had a liver disease which required medical treatment and Mr. B was admitted to the hospital. At the same time, Mr. B's family was informed by the same doctor that the patient had advanced inoperable liver cancer and was expected to live for only two or three months.

One month after hospitalization, an obstruction caused by the intestinal metastasis was discovered for which surgery was regarded as the best choice of treatment. In response to the explanation by the physician concerning the need for surgery, Mr. B stated, "I was told by my doctor that medical

treatment would be enough for my liver disease when I came to the hospital. I cannot understand why you are telling me now that I need surgery of the intestine which is different from liver disease. If this is the case, I am going home." At the same time, the patient's family responded to the physician, "You said that he had liver cancer. We do not understand why you want to operate on his intestine, because of an obstruction of the large intestine. Furthermore, we have no experience in these matters and do not understand your explanation. The only thing we can do is to leave everything to you and hope you will do the best."

In addition to the doctor's explanation, the nurses also explained to Mr. B's family and not to the patient that metastasis of liver cancer in which the liver is primarily lesion, might lead to an obstruction of the large intestine. The reason for surgery on the large intestine is to remove the blocked section of the intestine so that Mr. B's obstruction would be released. Together, the doctor and the nurses used simple language to explain to the patient (without the word cancer) and his family that the liver and the large intestine are a related system and work together in the digestion and absorption of food. The reason for surgery was to remove the tumor that formed in the large intestine which blocked the passage of the large intestine. With this explanation, the patient and his family decided to accept and consent to the surgery.

Mr. B's case illustrates some of the controversial problems related to informed consent, including the physician's judgment about how and to whom the diagnosis should be told. Also it addresses to what extent informed consent should be pursued, as well as the issue of "the doctor knows best" perception. The notion of "the doctor knows best" has remained a strong feeling among most of the Japanese community. Historically, most of the physicians in Japan are males who lead to a paternalistic attitude and also the medical code of conduct encourages the belief that medical treatment is best left to medical professionals. When considering the limited understanding of the patients and their family on illness and its treatment, this notion that "the doctor knows best" can be understood. But based on the principle of informed consent, it is important that the physician provide to the patient an explanation of the diagnosis, proposed treatment, and alternatives available to the patient, in an honest and simple language which can be understood by the patient. To do so will avoid misunderstanding and possible legal entanglement.

The decision to reveal or not to reveal the true diagnosis to the patient becomes a controversial problem in informed consent. In Japan, often the true diagnosis is not revealed to patients in an effort to shield them from distress.

From a social-cultural point of view, the case of not revealing the true diagnosis to the patient is often a common medical practice. The tendency is to explain the situation to the patient's family as a true diagnosis without informing the patient, particularly when the disease is untreatable. Leaving aside the problems of whether this is right or wrong, the case of Mr. B and his family posed the question "Why do I need intestinal surgery when I have a liver disease?" The physician was obliged to provide a full explanation to the patient and his family including the possible risks, benefits, post-surgery therapy, and alternative care. During the physician's explanation, it is vital that the nurse is present with the physician so that the nurse is able to support the patient and the family and witness the signature for informed consent.

Criteria for Informed Consent

As illustrated in the above cases, nurses need to understand clearly what is informed consent. The following criteria may assist nurses in their dealing with informed consent.

1) Informed consent must be written (unless oral consent can be proved in court).
2) Informed consent must be signed by the patient, or in the case of minors the person legally responsible for the patient.
3) The nurse must be aware that consent is not informed if the explanation of treatment or procedures was given when the patient was too sleepy or too distraught to process the information.
4) Consent is not informed if a sedative or pre-operative medication has been given to the patient before the explanation.
5) Consent is not informed if the explanation was so

technical that it could not be comprehended by the patient.

6) Informed consent requires that the procedure performed should the one to which consent was given.
7) Informed consent requires that the essential elements are presented including:
   a) an explanation of the condition;
   b) a fair explanation of the procedures to be used and the consequences;
   c) a description of alternative treatment or procedures;
   d) a description of the benefits to be expected;
   e) an offer to answer the patient's inquiries;
   f) freedom from coercion or unfair persuasions and inducement; and
   g) consent is not needed for emergency care if there is an immediate threat to life and health if medical experts agree that it is an emergency.

The Nurse's Role in Informed Consent

What is the nurse's role in informed consent? Is it to provide or add information before or after the doctor's explanation has been given? Is it to refer the patient to the doctor, or is it to avoid any participation? The advice given varies. Some suggest that getting involved in informed consent is simply not the nurse's role and is best left to the doctor; others consider it a professional responsibility. (Kelly, 1992)

It is generally agreed that nurses do not have the primary responsibility for getting informed consent. However, in nursing practice, it is noted that nurses as a practical matter typically have a central role in the process of providing the patient with information. In Japan where the nurse midwife has independent practices, they have the full responsibility for informing the patient about the patient's condition, tests, and treatment, and obtaining the patient's consent. Both the doctor and nurse are held liable. There are many questions patients may ask nurses. For example, some of the questions may be:

1) "What are you (nurse) doing to me (patient) and what are your qualifications?" The nurse should answer honestly.
2) "What does the doctor mean?" If the nurse is interpreting what the doctor said, it should be explained to the patient in lay terms the patient can understand.
3) "What is wrong with me?" The nurse should not answer directly. If the patient lacks information, they should always discuss with the doctor to clarifying concerns and questions.

If nurses give further information, it should be totally accurate and carefully recorded and the fact that should be shared with the doctor and other members of the medical team.

If the patient is coaxed or coerced into signing without an explanation, the consent is invalid. If the patient withdraws consent even verbally, the nurse is responsible for reporting this and ensuring that the patient is not treated. This is a legal responsibility not only to the patient but also to the hospital which can be held liable.

Often nurses may be asked to witness the signature without being present during the physician's explanations to the patient. Nurses should be very clear as to what they are witnessing, i.e., witnessing the signature only, which is without knowledge of the doctor's explanation, or witnessing the patient's signature when witnessing informed consent, which is when the nurse was present during the doctor's explanations to the patient.

The nurse's specific responsibility is to explain nursing care, including why and how of the nursing procedures even though this is not a legal requirement. It will assist the patient's understanding and cooperation during their hospitalization.

Summary

The written consent form is generally accepted as the legal affirmation that the patient has agreed to a particular test, procedure or treatment. Informed consent means that before the patient or legal guardian signs the consent form, the patient must have received sufficient information concerning the health care proposed, possible risks, benefits, and acceptable alternatives. The consent the patient or the legal guardian gives must be voluntary and enable them to decide either to accept or decline the proposed treatment. Yet, there are still problems surrounding

informed consent. Answers to these problems vary according to the medical practice code of the country and hospital policy where the nurses are employed.

The fundamental responsibility that nurses have to the patients and their families is to ensure that each individual understand the physician's explanation and that the individual have the right to decide freely whether or not to accept the therapy.

In general, nurses do not have the primary responsibility for getting informed consent. However, nurse midwives who practice independent care must obtain informed consent as would a physician. The nurse's specific responsibility in informed consent is to explain nursing care.

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